DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 25, 2014

Lepu Medical Technology (Beijing) Co., Ltd.
% Arthur Goddard
President
1531 Felton Road
South Euclid, Ohio 44121

Re: K140768
Trade/Device Name: Type I Brilliant Introducer Kit, Type II Brilliant Introducer Kit, Type IIi Brilliant Introducer Kit, Type IV Brilliant
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: October 3, 2014
Received: October 8, 2014

Dear Arthur Goddard,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 4: Indication for Use Summary

510(k) Number (if known): K140768

Device Name: Brilliant™ Introducer Kit

Indications For Use:

The Brilliant™ Introducer Kits are intended for use to facilitate the introduction of guide wires, catheters and other accessory medical devices through the skin into a vein or artery and minimize blood loss associated with such introduction.

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary: K140768

The Summary of Safety and Effectiveness information on the Brilliant™ Introducer Kit is being submitted in accordance with the requirements of 21 C.F.R. §807.92 and reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant: **Telephone:**	Lepu Medical Technology (Beijing) Co., Ltd. No. 37 Chaoqian Road Changping District, Beijing 102200 P.R. China +86-10-80120641
Contact:	Kim Xiangdan
Date:	March 24, 2014
Name:	Brilliant™ Introducer Kit
Classification Name:	Catheter Introducer, 870.1340
Product Code:	DYB
Predicate:	ShoocinTM Introducer Kit, Lepu Medical Technology, Ltd., K123475 with market clearance date of February 3, 2013.
Description:	The Brilliant™ Introducer Kit classifies into four types (Type I, II, III, and IV). Type I and II consists of a sheath introducer, a dilator, a guide wire with a guide wire collimator, a puncture needle; Type III consists of a sheath introducer, a dilator, a guide wire with a guide wire collimator; and Type IV consists of a sheath introducer, a dilator, a guide wire with a guide wire collimator, an intravascular catheter with introducer needle, a scalpel and a syringe. The puncture needle or an intravascular catheter incorporates a lumen, which provides a conduit for the insertion of the guide wire into the vascular system. The various types of guide wires, model dependent, are utilized as a guiding mechanism for the insertion of the introduction sheath into the vascular system. The guide wire contains a wire collimator, which assists in funneling the wire through the lumen of the puncture needle or the intravascular catheter and contains marking that are visible under fluoroscopy, which can determine the length of the guide wire within the vascular system. The sheath introducer provides a conduit for introducing other interventional devices, including guide wires and interventional catheters, into the vasculature. The main components of the sheath introducer assembly are a hydrophilic coated sheath introducer, hemostasis valve housing, and a side port with tubing connected to a 3-way stopcock/valve. The hydrophilic coated dilator is used to provide support and stability to the sheath introducer during deployment into the vascular system. The proximal end of the dilator includes a luer port and has a tapered, atraumatic distal tip. Both the sheath and dilator contain bismuth, making these devices visible under fluoroscopy.
Intended Use:	The Brilliant™ Introducer Kits are intended for use to facilitate the introduction of guide wires, catheters and other accessory medical devices through the skin into a vein or artery and minimize blood loss associated with such introduction.

Section 5: 510k) Summary

Specification Comparison:

The Brilliant™ Introducer Kit specifications are similar to the Shoocin™ Introducer Kit (K123475) and the differences do not raise any new issues of safety or effectiveness.

	Brilliant™	**Shoocin™**
Sheath Diameter:	4F through 7F	4F through 11F
Sheath Length:	7cm – 24cm	7cm – 23cm
Guide Wire Length:	45cm and 70cm	45cm and 80 cm
Guide Wire OD:	.018" – .035"	.018" – .038"
Introducer Needle:	20G and 22G	18 – 20G
Dilator:	12.5cm – 29.5cm	7cm – 23cm

Materials Comparison:

The Brilliant™ Introducer Kit materials have been subjected to biocompatibility tests and the differences between the Shoocin™ Introducer Kit (K123475 do not raise any new issues of safety or effectiveness.

	Brilliant™	**Shoocin™**
Needle:	Stainless Steel	Stainless Steel
Needle Luer:	Polycarbonate	Polycarbonate
Guide Wire:	Stainless Steel, Stainless Steel w/nitinol core, or Polyurethane jacket w/nitinol coil	Stainless Steel
Guide Wire Collimator:	Polycarbonate	Polycarbonate
Dilator Tube:	Polycarbonate	Polypropylene
Dilator Luer:	Acrylobutyistyrene	Acrylobutyistyrene
Outer Sheath:	Fluorinated Ethylene Propylene	Fluorinated Ethylene Propylene
Sheath base:	Acrylobutyistyrene	Acrylobutyistyrene
Side Port Tubing	Polyurethane	Polyurethane
Hemostasis Valve:	Silicone	Silicone
3-Way Stop Cock: Cap: Valve:	Acrylobutyistyrene Polyethylene Polyethylene	Acrylobutyistyrene Polyethylene Polyethylene

Sterilization:

The method used is based on practices recommended by AAMI / ANSI / ISO 11135:2007 and provides a Sterility Assurance Level (SAL) of 10^{-6}

Shelf Life:

In accordance with ISO 11070 the real time aging of Brilliant™ Introducer Kit demonstrated that the performance of the specific components met the standard requirements without any significant difference to product performance requirements before aging. So the product is stable and reliable within the two-year useful life.

Section 5: 510k) Summary

Biocompatibility:

The Brilliant™ Introducer Kit produced by Lepu Medical Technology was assessed against the International Standard ISO 10993-1, "Biological evaluation of medical devices. Part 1. Guidance on selection of tests." The Shoocin™ Introducer Kit would be classified as an External Communicating Device in contact with the Circulating Blood for a Limited Duration (<24 hours). The following test would be required for any patient / user contacting material:

Test	Standard	Results
Hemolysis	ISO 10993-4	Both the test article in direct contact with blood and the test article extract were non-hemolytic.
Cytotoxicity	ISO 10993-5	The test article extract showed no evidence of causing cell lysis or toxicity.
Maximum Sensitization	ISO 10993-10	The test article was not considered a sensitizer in the guinea pig maximization test.
Intracutaneous Irritation	ISO 10993-10	The test article met the requirements for the SC and SO test extracts.
Systemic Toxicity	ISO 10993-11	There was no mortality or evidence of systemic toxicity from the extracts injected into mice.
USP Pyrogen Study	ISO 10993-11	The test article was judged as nonpyrogenic.
In Vivo Thromboresistance	ISO 10993-4	Under conditions of the study of extreme exaggeration of clinical use, the test article was not thromboresistant and the control article was thromboresistant.
Partial Thromboplastin Time	ISO 10993-4	The test article would be considered a minimal activator and met the requirements of the test.
C3a Complement Activation Assay	ISO 10993-4:	The test article was not considered to be a potential activator of the complement system.
SC5b-9 Complement Activation Assay	ISO 10993-4:	The test article was not considered to be a potential activator of the complement system.

Section 5: 510k) Summary

Performance Testing:

The Brilliant™ Introducer Kit successfully passed all of the following performance tests:

Brilliant™ Introducer Kit Performance Testing	
Sheath Introducer	Sheath Introducer should be free of defects
	Sheath Introducer ID
	Sheath Introducer Effective Length
	Radiodetectability
	Dilator accessibility
	Fracture Strength Test
	Leaking Performance Test
	Coating Efficacy Test
	Coating Integrity Test

Performance Testing:

The Brilliant™ Introducer Kit successfully passed all of the following performance tests:

Brilliant™ Introducer Kit Performance Testing	
Dilator	Dilator should be free of defects
	Dilator OD
	Dilator ID
	Dilator Effective Length
	Radiodetectability
	Guide wire accessibility
	Fracture Strength Test
	Coating Efficacy Test
	Coating Integrity
Guide wire	Surface free from impurity
	Guide wire length
	Guide wire OD
	Radiodetectability
	Corrosion Resistance
	Fracture Strength Test
	Flexing Resistance Test
	Associative Guide Wire Strength Test
	Coating Integrity
Puncture Needle	Surface free from defects
	Needle OD
	Needle ID
	Needle Effective Length
	Accessibility – Guide wire
	Corrosion Resistance
	Joint Strength – Needle to hub

Section 5: 510k) Summary

Substantial Equivalency Information:	The information provided in this submission, comparing intended use, principle of operation and performance, the Brilliant™ Introducer Kit device is substantially equivalent to existing legally marketed device.
Conclusion:	The information provided in this submission and comparing intended use, principle of operation and overall technological characteristics (i.e. puncture needle, guide wire, dilator, and sheath introducer to obtain access to the vascular system), the Brilliant™ Introducer Kit supports a determination of substantially equivalent to existing legally marketed predicate device Shoocin ™ Introducer Kit. Any technological differences between the Brilliant™ Introducer Kit and the predicate Shoocin™ Introducer Kit do not raise new questions of safety or effectiveness.